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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,689	03/24/2004	Gyula Hadlaczky	24601-402P	6587

7590 05/08/2006

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EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,689	HADLACZKY, GYULA	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDS, 09/17/2004, 10/21/2004, 06/06/2005, 09/28/2005, 11/18/2005, 03/31/2006.

DETAILED ACTION

Claim Rejections - 35 USC § 101

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4 and 9-13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 and 6-10 of copending Application No. 10219694. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-24 are drawn to a method for amplifying nucleic acid comprising introducing any nucleic acid molecule into a plant cell wherein the nucleic acid molecule includes any sequence of nucleotides that targets the molecule to any amplifiable region of the chromosome in the cell, growing the cell, and identifying from the resulting cells those that include a chromosome with a portion that has undergone amplification, wherein the targeting sequence of nucleotide(s) is selected from those that target the molecule to the pericentric heterochromatic region of the chromosome, or comprises rDNA, or comprises an amplification promoting sequence. The claims are further drawn to the method above wherein the nucleic acid encodes one or more genes wherein disease resistance is conferred upon the plant, wherein the portion that has undergone amplification comprises the introduced nucleic acid molecule, and wherein the portion that has undergone amplification comprises centromeric nucleic acid, pericentric heterochromatin, or a heterologous nucleic acid. The claims are further drawn to the method above wherein the introduced nucleic acid molecule comprises a selectable marker.

In contrast, the specification only provides guidance for the amplification of mammalian nucleic acid sequences in mammalian cells with mammalian targeting

sequences. The specification does not provide guidance for the amplification of any plant sequences or any plant targeting sequences. The specification further does not provide guidance to any amplifiable regions of a plant chromosome.

No amplification-stimulating DNA elements, and therefore no targeting DNA sequences to amplifiable regions of the chromosome in plants, were known and/or disclosed at the time of the invention to enable one to make or use the invention. Borisjuk et al (2000 Nature Biotechnology 18:1303-1306) disclosed a specific sequence in the intergenic spacer region of the rDNA of tobacco that stimulates amplification of DNA sequences. However, up until the time of this article, the art was silent on any plant sequences that stimulate the amplification of adjacent DNA sequences, and furthermore, Borisjuk et al state "However, until this report, no amplification-stimulating DNA elements from plants have been identified thus far. Moreover, directed amplification of heterologous genes has never been achieved in transgenic multicellular organisms such as plants" (see page 1303, second column, first paragraph, for example). Given this disclosure and the lack of guidance in the specification, it would have been undue experimentation for one of skill in the art to sequence and evaluate a multitude of divergent plant genomes for amplification-stimulating sequences to determine the targeting sequences that would lead to the amplification of DNA.

Furthermore, "a sequence of nucleotides" broadly claims a multitude of DNA sequences and "an amplifiable region of the chromosome" broadly claims a multitude of chromosomal regions and sequences for targeting. Undue experimentation would be required by one of skill in the art to evaluate all regions of plant chromosomes and all

sequences of nucleotides as broadly claimed for the ability to target a DNA molecule to an amplifiable region of the chromosome. Absent a SEQ ID NO, undue experimentation would be required for one of skill in the art to make and use the invention.

Even if the sequences and regions were clearly defined by Applicant, the only disclosed function for the amplification of nucleic acids is in the construction of an artificial chromosome. However, the function of even a clearly defined rDNA region in plants is unpredictable. Donald et al (1997 Genome 40:674-681) disclose that the B chromosome ribosomal DNA is not transcribed in the leaf tissue of Brachycome dichromosomatica (see page 679 second and third paragraphs, for example). Undue experimentation would be required to determine the function of each rDNA sequence from all of the claimed plant species and chromosomes and to determine a use for plant cells transformed therewith. The function of a centromeric region, is likewise unpredictable. Hall et al (2004 Current Opinion in Plant Biology 7:108-114) in a comprehensive review of plant centromeres discuss the field of plant centromeres and point out that although studies implicate satellites and retro-elements as important DNA sequences for centromere function, potential roles for other sequences have not been ruled out (see page 112, 3rd paragraph, for example). Furthermore, Hall et al teach that efforts to sequence the rice and maize centromeres were not complete as of the date of publication, and therefore all centromeric sequences as broadly claimed could not have been known at the time of invention (see page 109 first paragraph). Undue experimentation would be required to isolate, sequence, and evaluate all plant

sequences for their ability to function as a centromere, or for their presence at the centromeric region of the chromosome.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate all targeting sequences and all amplifiable regions of the plant chromosome as claimed (see Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984) where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation).

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1-24 are drawn to a method for amplifying nucleic acid comprising introducing any nucleic acid molecule into a plant cell wherein the nucleic acid molecule includes any sequence of nucleotides that targets the molecule to any amplifiable region of the chromosome in the cell, growing the cell, and identifying from the resulting cells those that include a chromosome with a portion that has undergone amplification, wherein the targeting sequence of nucleotide(s) is selected from those that target the molecule to the pericentric heterochromatic region of the chromosome, or comprises rDNA, or comprises an amplification promoting sequence. The claims are further drawn to the method above wherein the nucleic acid encodes one or more genes wherein

disease resistance is conferred upon the plant, wherein the portion that has undergone amplification comprises the introduced nucleic acid molecule, and wherein the portion that has undergone amplification comprises centromeric nucleic acid, pericentric heterochromatin, or a heterologous nucleic acid. The claims are further drawn to the method above wherein the introduced nucleic acid molecule comprises a selectable marker.

In contrast, the specification only provides guidance for the amplification of mammalian nucleic acid sequences in mammalian cells with mammalian targeting sequences. The specification does not provide guidance for the amplification of any plant sequences or any plant targeting sequences. The specification further does not provide guidance to any amplifiable regions of a plant chromosome.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 and 18-24 are drawn to a method for amplifying nucleic acid comprising introducing a nucleic acid molecule into a plant cell, wherein the nucleic acid molecule includes a sequence of nucleotides that targets it to an amplifiable region of a chromosome in the cell, growing the cell, and identifying from among the resulting cells those that include a chromosome with "a portion" that has undergone amplification.

It is unclear to the Examiner what "a portion" is referring to. In addition to being broad claim language in which "a portion" is not clearly defined and could mean as little as a single nucleotide, it is also unclear what part of the chromosome "a portion" refers to. As written, "a portion" could mean any part of any chromosome in the cell and would not even be limited to DNA sequence since it is not particularly mentioned.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 9-10, 14, 18-19, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Assaad et al (1992 Genetics 132:553-566).

Claims 1, 5-7, 9-10, 14, 18-19, and 22-24 are drawn to a method for amplifying nucleic acid comprising introducing any nucleic acid molecule into a plant cell, wherein the nucleic acid molecule includes "a sequence" of nucleotides that targets it to "an amplifiable" region of a chromosome in the cell under conditions whereby the fragment integrates into the chromosome and further comprises replicating the cell, growing the cell, and identifying from among the resulting cells those that include a chromosome with a portion that has undergone amplification, wherein the introduced nucleic acid molecule comprises one or more genes, a selectable marker and a heterologous nucleic acid. The term "an amplifiable" region of the chromosome as defined by applicant includes any region whereby two or more copies of the DNA are produced which may occur during replication, which would include any area of the chromosome that undergoes replication during cell division (see e.g., page 19, lines 9-19 of the specification).

Assaad et al teach a transgenic Arabidopsis plant in which neomycin phosphotransferase is integrated into the chromosome by homologous recombination, the cells are grown and the resulting cells are identified that have undergone transgene

amplification by growth on hygromycin (see page 555 first full paragraph, and last paragraph, for example).

Claim Rejections - 35 USC § 103

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10219694.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the invention of a method for amplifying DNA by introducing a nucleic acid molecule into a plant cell wherein a sequence of nucleotides, including rDNA and APS target the nucleic acid molecule to

an amplifiable region of the chromosome in a plant cell. The differences between the claims involve subject matter that is well known in the art, including choice of transformable host species, and therefore modification would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt et al (US patent 4801540).

Claim 8 is drawn to a method for amplifying nucleic acid comprising introducing any nucleic acid molecule into a plant cell, wherein the nucleic acid molecule includes "a sequence" of nucleotides that targets it to "an amplifiable" region of a chromosome in the cell, growing the cell, and identifying from among the resulting cells those that include a chromosome with a portion that has undergone amplification, wherein the introduced nucleic acid molecule encodes products that confer disease resistance to a plant. The term "an amplifiable" region of the chromosome as defined by applicant includes any region whereby two or more copies of the DNA are produced which may occur during replication, which would include any area of the chromosome that

undergoes replication during cell division (see e.g., page 19, lines 9-19 of the specification).

Hiatt et al teach introduction of the PG gene into a plant via homologous recombination, wherein the genome of the plant contains the PG gene and would inherently be "amplified" through cell division (see claims 1, 3, 9, 14, column 4 lines 6-15, for example). Hiatt et al also suggest using the PG transgene by expressing the gene in anti-sense orientation for the inhibition of PG in plant cells for the purposes of disease resistance (see column 3 lines 14-19 and columns 4 and 5 lines 65 of column 4 to line 3 of column 5, for example).

Given the state of the art, and the disclosure by Hiatt et al, it would have been obvious to one of ordinary skill in the art to use the methods of transformation and homologous recombination disclosed by Hiatt et al to transform a plant cell with the nucleic acid molecule comprising the PG gene sequence in anti-sense orientation as further suggested by Hiatt et al.

No claim is allowed.

Claims 2-4, 11-13, 15-17, and 20-21 are free of the prior art given the failure of the prior art to teach or reasonably suggest using rDNA or an APS as targeting sequences to an amplifiable region of the chromosome including the pericentric heterochromatic region, whereby the portion of the chromosome undergoing amplification comprises centromeric nucleic acid or pericentric heterochromatin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638